Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives
John E. Baldacci, Governor Brenda M. Harvey, Commissioner

Department of Health and Human Services
Licensing and Regulatory Services
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DATE: December 28, 2009

TO: Interested Parties

FROM: Catherine Cobb, Director, Division of Licensing and Regulatory Services

SUBJECT: PROPOSED **Rules Governing the Reporting of Sentinel Events**
10-144 CMR Chapter 114.
Comment deadline: January 30, 2010. [No public hearing.]

New Feature: Submit comments online!
Go to:http://www.maine.gov/dhhs/dlrs/rulemaking/proposed.shtml
Now you may submit comments online, via email, via fax, or via postal service.

PROPOSED Rules Governing the Reporting of Sentinel Events
To reduce medical errors and improve patient safety, the Maine Legislature enacted Public Law 2009, Chapter 358 which amended the Sentinel Events Reporting statute, 22 MRSA Chapter 1684. The rules have been amended to incorporate the changes. The amended rule includes the following changes:

- New definitions including definitions of root cause analysis, immediate jeopardy, and near miss;
- The definition of sentinel events is amended to include the list of serious and preventable events identified by the National Quality Forum;
- Requires standardized reporting, notification and provider/staff training procedures;
- The penalty for failure to report a sentinel event is increased from not more than $5000 to not more than $10,000; and
- Appendix I incorporates by reference "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report*. [*With permission.]*

The amended rules are available on line at:
http://www.maine.gov/dhhs/dlrs/rulemaking/proposed.shtml
To request a paper copy of the rules, please call (207) 287-9300 or 1-800-791-4080.

Notice of Agency Rule-making Proposal

AGENCY: **Division of Licensing and Regulatory Services, Department of Health and Human Services**

CHAPTER NUMBER AND TITLE:
10-144 C.M.R. Ch. 114, Rules Governing the Reporting of Sentinel Events

PROPOSED RULE NUMBER (*leave blank; assigned by Secretary of State*):

CONTACT PERSON FOR THIS FILING:
Anne Flanagan, Assistant Director, Division of Licensing and Regulatory Services
41 Anthony Avenue, Augusta, Maine 04333
(207) 287-9300 1-800-791-4080 TTY 1-800-606-0215
fax (207) 287-5815 Anne.Flanagan@maine.gov

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): **same**

PUBLIC HEARING (if any): **None scheduled** unless requested by 5 or more interested persons.

COMMENT DEADLINE: **January 30, 2010 at 5 pm.**

BRIEF *SUMMARY: **The amended rule includes the following changes: adds new definitions including definitions of root cause analysis, immediate jeopardy, and near miss; amends the definition of sentinel events to include the list of serious and preventable events identified by the National Quality Forum; requires standardized training of providers and staff, reporting and notification procedures; and Appendix I incorporates by reference "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report.* Proposed rules available on line at: http://www.maine.gov/dhhs/dlrs/public_hearings/home.html**

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): **none**

STATUTORY AUTHORITY FOR THIS RULE:
22 M.R.S.A. Chapter 1684, 22 M.R.S.A. §42, 22-A M.R.S.A. §205

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): **Maine Public Law 2009, Chapter 358.**

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: **same as contact person above.**

** Check one of the following two boxes.*

☐ *The above summary is for use in both the newspaper and website notices.*

☐ *The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.*

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT_____ DATE:_____

Catherine M. Cobb, Director, Division of Licensing and Regulatory Services

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
010	**10A**	**203601**	**6729**			

MAPA-3 revised 9-09: additional summary information for web

Notice of Agency Rule-making Proposal

DETAILED BASIS STATEMENT / SUMMARY:

Proposed Rule
10-144 C.M.R. Chapter 114
Rules Governing the Reporting of Sentinel Events

To reduce medical errors and improve patient safety, the Maine Legislature enacted Public Law 2009, Chapter 358 which amended the Sentinel Events Reporting statute, 22 MRSA Chapter 1684. The rules have been amended to incorporate the changes. The amended rule includes the following changes:

- New definitions including definitions of root cause analysis, immediate jeopardy, and near miss;
- The definition of sentinel events is amended to include the list of serious and preventable events identified by the National Quality Forum;
- Requires standardized training of providers and staff, reporting and notification procedures;
- The penalty for failure to report a sentinel event is increased from not more than $5000 to not more than $10,000; and
- Appendix I incorporates by reference "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report*.

The amended rules are available on line at:
http://www.maine.gov/dhhs/dlrs/public_hearings/home.html
To request a paper copy of the rules, please call (207) 287-9300 or 1-800-791-4080.

STATUTORY AUTHORITY

22 M.R.S.A. Chapters 405 and 1684
22 M.R.S.A. §42
22-A M.R.S.A. §205

Rules Governing the Reporting of Sentinel Events

10-144 CMR Chapter 114
Effective Date ~~January 1, 2009~~

Maine Department of Health and Human Services
Division of Licensing and Regulatory Services
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Purpose. The Regulations Governing the Reporting of Sentinel Events create a system for reporting all sentinel events to improve the quality of healthcare and increase patient safety. The reporting system focuses the attention of a healthcare facility on understanding the causes that underlie the event and on changing systems and processes to reduce the probability of future events.

Section 1. Definitions. As used in these rules, unless the context otherwise indicates, the following terms have the following meanings.

1.1 **Adverse.** For the purposes of these rules, "adverse" means a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

1.2 **Associated With.** For the purposes of these rules, "associated with" means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.

1.3 **Disability**. "Disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual. (see Americans with Disabilities Act).

1.4 **Discovered**. For the purposes of these rules, "discovered" means the point at which one becomes aware of an occurrence that triggers an action under these rules. ~~DLRS. "DLRS" means the Division of Licensing and Regulatory Services, Maine Department of Health and Human Services. The Sentinel Events Team (SET) is a unit of DLRS.~~

1.5 **Division.** "Division" means the Department of Health and Human Services (DHHS), Division of Licensing and Regulatory Services (DLRS).

1.6 **Event.** "Event" means a discrete, auditable, and clearly defined occurrence.

1.7 **Final Agency Action**. "Final Agency Action" means a decision by DHHS which affects the legal rights, duties or privileges of specific persons, which is dispositive of all issues, legal and factual, and for which no further recourse, appeal or review is provided within DHHS, 5 M.R.S.A. §8002.

1.8 ~~1.2~~**Healthcare Facility.** "Healthcare facility" or "facility" means ~~the following:~~ a state institution as defined by 34-B M.R.S.A. Chapter 1 or a healthcare facility licensed by the division, excluding a facility licensed as a nursing facility by 22 M.R.S.A. Chapter 405 or licensed as an assisted housing program by 22 M.R.S.A. Chapter 1664. "Healthcare facility" includes:

~~1.2.1State institutions including the Riverview Psychiatric Center and the Dorothea Dix Psychiatric Center (34-B M.R.S.A. Chapter 1);~~

1.8.1 ~~1.2.2All hospitals~~A general and specialty hospital licensed pursuant to 22 M.R.S.A. Chapter 405~~., including all service locations as indicated on the hospital license application;~~

1.8.2 ~~1.2.3~~ An ~~A~~ambulatory surgical facility ~~facilities~~ licensed pursuant to 22 M.R.S.A. § 1812-E.~~;~~

1.8.3 ~~.2.5~~An ~~E~~end-stage renal disease (ESRD) facility~~facilities~~ licensed pursuant to 22 M.R.S.A. Chapter 412. These rules do not apply to home dialysis. Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training.

1.8.4 ~~1.2.4~~An ~~I~~intermediate ~~C~~care facility~~Facilities~~ for ~~P~~persons with ~~M~~mental ~~R~~retardation or developmental disabilities ~~Nursing~~ (ICF/MR ~~Nursing~~) licensed pursuant to 22 M.R.S.A. Chapters ~~1 and~~ 405. ~~and the Elizabeth Levinson Center (34-B M.R.S.A. Chapter 1); and~~

~~1.2.6Healthcare facility does not include a facility licensed as a nursing facility pursuant to 22 M.R.S.A. Chapter 405, or assisted housing programs licensed pursuant to 22 M.R.S.A. Chapter 1664.~~

1.9 Hyperbilirubinemia. "Hyperbilirubinemia" means bilirubin levels greater than 30 mg/dl.

1.10 Hypoglycemia. "Hypoglycemia" means blood glucose levels less than 60 mg/dl.

1.11 Immediate jeopardy. "Immediate jeopardy" means a situation in which the provider's noncompliance with one or more conditions of participation in the federal Medicare program has caused, or is likely to cause, serious injury, harm or impairment to or death of a patient.

1.12 Inter-facility Transfer. "Inter-facility transfer" means any transfer, after initial assessment and stabilization of the patient, from, and to, a healthcare facility, or within the same health system, including but not limited to:

1.12.1 Hospital to hospital.

1.12.2 Clinic to hospital.

1.12.3 Hospital to rehabilitation facility.

1.12.4 Ambulatory surgical facility to hospital.

1.12.5 Hospital to long term care.

1.12.6 ESRD to hospital.

1.13 **Major Life Activities.** For the purposes of these rules, "major life activities" means functions, including but not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, working and the operation of a major bodily function. Major bodily functions include but are not limited to functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.

1.14 ~~1.3~~**Major Permanent Loss of Function.** "Major permanent loss of function" means ~~-~~sensory, motor, physiological or intellectual impairment that was not present at the time of admission and

1.4.1 ~~1.3.1~~requires continued treatment or~~-~~

1.4.2 ~~1.3.2~~ imposes persistent major restrictions in activities of daily living.

1.15 **Near Miss Event.** "Near miss" means an event or situation that did not produce patient injury, but only because of chance, which may include, but is not limited to, robustness of the patient or a fortuitous, timely intervention.

1.16 **Neonate.** "Neonate" means the first 28 days of life.

1.17 **Perinatal Period. "**Perinatal period" means the 28th week of gestation to the 28th day of life**.**

1.18 **Pregnancy, High Risk.** "High risk pregnancy" means a pregnancy in which the mother or the developing fetus has a condition that places one or both of them at a higher-than-normal-risk for complications, either during the pregnancy (antepartum), during delivery (intrapartum), or following the birth (postpartum).

1.19 **Pregnancy, Low Risk.** "Low risk pregnancy" means a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other

previously documented condition that poses a high risk of poor pregnancy outcome.

1.20 **Preventable**. For the purposes of these rules "preventable" means an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

1.21 ~~1.4~~**Root Cause Analysis (RCA).** "Root cause analysis"~~(RCA)~~ means a structured process for identifying the ~~basic or~~ causal or contributing factors underlying adverse events. The RCA follows a predefined protocol for identifying the specific factors in causal categories. ~~that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. RCA focuses primarily on systems and processes, not on individual performance. RCA progresses from causes in clinical processes to causes in organizational systems. Improvements are identified that would tend to decrease the likelihood of such events in the future.~~

1.22 **Sentinel Event**. A "sentinel event" means:

1.22.1 An unanticipated death, or patient transfer to another health care facility, unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility;

1.22.2 A major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility that is present at the time of the discharge of the patient. For the purposes of ESRDs, the term "discharge" means within 24 hours of a treatment. If within 2 weeks of discharge from the facility, evidence is discovered that the major loss of function was not permanent, the health care facility is not required to submit a report pursuant to 22 M.R.S.A. § 8753 (2);

1.22.3 An unanticipated perinatal death or major permanent loss of function in an infant, with a birth weight over 2,500 grams that is unrelated to the natural course of the infant's or mother's illness or underlying condition or unrelated to the proper treatment of the infant's or mother's illness or underlying condition in a healthcare facility; and

1.22.4 Other serious and preventable events listed here and in Appendix I of these rules pursuant to 22 M.R.S.A. §8752 (4-A) (D). Appendix I incorporates by reference "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report*.

In addition to its availability in Appendix I of these rules, copies of "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report* may be found at http://www.qualityforum.org/Topics/Safety.aspx or may be obtained at cost from the Maine DHHS, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333.

Failure to comply with the specifications and guidance in "Table 1 – List of Serious Reportable Events, pages 7-16" of the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report* in Appendix I constitutes a violation of these rules.

1.22.4.1 Surgical Events

1.22.4.1.1. Surgery performed on the wrong body part.

1.22.4.1.2 Surgery performed on the wrong patient.

1.22.4.1.3 Wrong surgical procedure performed on a patient.

1.22.4.1.4 Unintended retention of a foreign object in a patient after surgery or other procedure.

1.22.4.1.5 Intraoperative or immediately postoperative death in an ASA Class 1 patient. ASA Class 1 patient is an acronym for "American Society of Anesthesiologists Classification 1 (Normal Healthy Patient)".

1.22.4.2 Product or Device Events

1.22.4.2.1 Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.

1.22.4.2.2 Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.

1.22.4.2.3 Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

1.22.4.3 Patient Protection Events

1.22.4.3.1 Infant discharged to the wrong person.

1.22.4.3.2 Patient death or serious disability associated with patient elopement (disappearance).

1.22.4.3.3 Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

1.22.4.4 Patient Treatment Events

1.22.4.4.1 Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).

1.22.4.4.2 Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.

1.22.4.4.3 Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.

1.22.4.4.4 Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.

1. 2.4.4.5 Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.

1.22.4.4.6 Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.

1.22.4.4.7 Patient death or serious disability due to spinal manipulative therapy.

1.22.4.4.8 Artificial insemination with the wrong donor sperm or wrong egg.

1.22.4.5 Environmental Events

1.22.4.5.1 Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.

1.22.4.5.2 Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

1.22.4.5.3 Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.

1.22.4.5.4 Patient death or serious disability associated with a fall while being cared for in a healthcare facility.

1.22.4.5.5 Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

1.22.4.6 Criminal Events

1.22.4.6.1 Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

1.22.4.6.2 Abduction of a patient of any age.

1.22.4.6.3 Sexual assault on a patient within or on the grounds of a healthcare facility.

1.22.4.6.3.1 If *one or more* of the following criteria is met, the facility is required to submit notification regarding a sexual assault:

1.22.4.6.3.2 Any staff-witnessed sexual assault.

1.22.4.6.3.3 Sufficient clinical evidence obtained by the healthcare facility to support allegations of sexual assault.

1.22.4.6.3.4 Admission by the perpetrator of a sexual assault that occurred on the premises.

1.22.4.6.4 Death or a significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility.

1.23 **Sentinel Events Team.** The Sentinel Events Team (SET), a unit of the Division of Licensing and Regulatory Services (DLRS), is assigned the responsibility to implement these rules.

1.24 **Serious**. For the purposes of these rules, "serious' means an event that results in death or loss of a body part, disability or loss of bodily function lasting more that seven days or still present at the time of discharge from a facility or, when referring to other than an adverse event, an event the occurrence of which is not trivial.

1.25 **Sexual Assault**. "Sexual assault" as a reportable event means unconsented sexual contact that is not part of medically necessary health care involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the healthcare facility, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ or object.

1.26 **Spinal Manipulative Therapy.** "Spinal manipulative therapy" means all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.

1.27 **Surgery.** "Surgery" means an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice.

~~1.5 Sentinel Event. A "sentinel event" means:~~

~~1.5.1 An unanticipated death that is determined:~~

~~1.5.1.1 to be unrelated to the natural course of the patient's illness or underlying condition; or~~

~~1.5.1.2 to be unrelated to the proper treatment of the patient's illness or underlying condition; or~~

~~1..5.1.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).~~

~~1.5.2 A major permanent loss of function, as defined in section 1.3, that is not present when the patient is admitted to the health care facility that is determined:~~

~~1.5.2.1 to be unrelated to the natural course of the patient's illness or underlying condition; or~~

~~1.5.2.2 to be unrelated to the proper treatment of the patient's illness or underlying condition; or~~

~~1..5.2.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).~~

~~1.5.3 Surgery on the wrong patient or wrong body part;~~

~~1.5.4 Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities;~~

~~1.4.5 Suicide of a patient in a health care facility where the patient receives inpatient care;~~

~~1.5.6 Infant abduction or discharge to the wrong family; or~~

~~1.5.7 Rape of a patient. Rape, as a reportable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the health care facility, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ or object. One or more of the following must be present to determine reportability:~~

~~1.5.7.1 Any staff-witnessed sexual contact as described above.~~

~~1.5.7.2 Sufficient clinical evidence obtained by the health care facility to support allegations of unconsented sexual contact.~~

~~1.5.7.3 Admission by the perpetrator that sexual contact, as described above, occurred on the premises.~~

~~1.6Sentinel Events Reporting System. "Sentinel events reporting system" means a system for reporting sentinel events for the purpose of improving the quality of healthcare and increasing patient safety.~~

Section 2. Facility Responsibilities. ~~Mandatory Reporting of Sentinel Events~~

2.1 Notification and Reporting System. A healthcare facility must have a Sentinel Event Notification and Reporting System that includes but is not limited to:

2.1.1 Discovery Policy. A Discovery System with policies and procedures that detail a systematic process for identifying specific categories of cases including but not limited to Near Miss Events (Section 1.15), Serious Adverse Events, and events that resulted in a sentinel event (Section 1.22). The written policies and procedures must include but are not limited to the following:

2.1.1.1 Copy of the current Sentinel Events Reporting law, 22 M.R.S.A. Chapter 1684.

2.1.1.2 Copy of the current Rules Governing the Reporting of Sentinel Events, 10-144 C.M.R. Ch. 114.

2.1.1.3 Preservation of evidence procedures, including but not limited to the following:

2.1.1.3.1 Procedure for sequestering equipment involved in the event.

2.1.1.3.2 Procedure for sequestering other evidence including but not limited to medication vials and intravenous (IV) administration bags.

2.1.1.4 Procedure for identifying clinical indications for requesting an autopsy.

2.1.1.5 Procedure for review of death logs, transfer logs, patient complaints, patient records submitted for case review, and resuscitation reviews.

2.1.2 Notification Policy. Facility sentinel event notification policies and procedures that include but are not limited to the following:

2.1.2.1 Facility procedure for notifying the SET.

2.1.2.2 Facility procedure that identifies the person responsible in the facility for the notification of the SET and, in the absence of that person, the identification of the alternate person responsible for the notification of the SET.

2.1.3 Investigation and Reporting Policies. Facility investigation and reporting policies and procedures including but not limited to the following:

2.1.3.1 Facility procedure for conducting a RCA.

2.1.3.2 Facility procedure that ensures corrective actions are implemented and evaluated for effectiveness.

2.2 **Staff Education.** Maintain documentation of education during new employee orientation and annually to staff, and individuals with privileges, at all levels regarding:

2.2.1 The facility's Sentinel Event Notification and Reporting System.

2.2.2 Maine rules regarding mandatory reporting of sentinel events, the voluntary reporting of near miss events, and the standardized procedures for notification and reporting.

2.2.3 Facility internal processes for notifying leadership.

2.2.4 Facility responsibility to implement action plans.

2.2.5 Facility responsibility to annually attest that all sentinel events were reported to the SET.

2.3 **Cooperation.** A healthcare facility that has filed a notification or a report of the occurrence of a sentinel event, pursuant to these rules, must cooperate with the division as necessary for the division to fulfill its duties described in 22 M.R.S.A. § 8754. All information collected or developed as a result of an initial or onsite SET review is confidential and privileged information.

2.4 ~~2.7~~ **Annual Attestation**~~notification~~**.** By January 30TH of each year, on a department-approved form~~approved by the SET~~, each healthcare facility must send the SET a written attestation ~~notice~~ that contains an affirmative statement that it reported~~, in accordance with Section 2.2,~~ all sentinel events that occurred in the prior calendar year.

~~2.1 Sentinel Events Team. The Sentinel Events Team (SET), a unit of the Division of Licensing and Regulatory Services (DLRS), is assigned the responsibility to implement these rules.~~

~~2.2 Mandatory report. A healthcare facility is mandated to notify the SET of a sentinel event that occurs in the healthcare facility as defined in Section 1.2 of~~

these rules. If a facility has reasonable cause to believe that a sentinel event may have occurred, it may confer with the SET, which shall determine whether the event is reportable.

2.3 Notification. The health care facility must notify the SET of the occurrence of a sentinel event by the next business day after the sentinel event occurred or the next business day after the facility determines that the event occurred. The written notification must include the following information:

2.3.1 Name of the health care facility;

2.3.2 Type of sentinel event as defined in Section 1.5 above;

2.3.3 Date and time of the sentinel event; and

2.3.4 Date and time of notification.

2.4 Written report. A health care facility must file a written report with the SET no later than forty-five (45) days following the notification of the occurrence of a sentinel event. The written report must contain the following information:

2.4.1 The health care facility name and address;

2.4.2 The name, title, telephone number, email address, and fax number of the contact person designated by the health care facility;

2.4.3 The date and time of the sentinel event;

2.4.4 The type of sentinel event, as defined in Section 1.5 above, and a brief description of the sentinel event;

2.4.5 A copy of a thorough and credible RCA. See Section 1.4.

2.4.6 Identification of changes that could be made to reduce the risk of the sentinel event occurring in the future;

2.4.7 A brief description of any corrective action taken or planned;

2.4.8 The signature of the chief executive officer of the health care facility.

2.5 SET acceptance of report. The SET will determine if the written report is acceptable.

~~2.6 Immunity. A person who in good faith reports a sentinel event in accordance with these rules is immune from any civil or criminal liability for the act of reporting or participating in the review by DLRS. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. These rules may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.~~

Section 3. Standardized Procedures. ~~SET Review Procedure of Sentinel Events~~

3.1 Notification by next business day. The healthcare facility must notify the SET of a sentinel event (Section 1.22) by the next business day after the event occurred or the next business day after the facility discovers that the event occurred.

3.2 Notification Procedure. Immediately upon discovery of a sentinel event, the facility must act in accordance with its notification procedures as required by Section 2.1 of these rules.

3.2.1 Notification of the discovery of a sentinel event must not be delayed secondary to internal deliberations or pending autopsy or medical examiner results.

3.2.2 Within 1 business day of the discovery of a sentinel event, the healthcare facility must send a facsimile of the department-approved sentinel event notification form to the SET.

3.2.3 The day the notification facsimile is sent to the SET, the facility must telephone the SET to confirm its receipt of the notification facsimile and, at the discretion of the SET, schedule an on-site SET visit.

3.3 Situational Notification Considerations.

3.3.1 Inter-facility Transfer Notification. A sending facility is required to submit to the SET notification regarding a sentinel event when the transfer to another facility is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in their healthcare facility.

3.3.2 Discharge Follow-up Notification.

3.3.2.1 A facility is required to submit to the SET notification regarding a sentinel event involving a patient with a major permanent loss of function that is present at the time of discharge.

3.3.2.1.1 Within 14 days of discharge from a health care facility, if evidence is discovered that the major loss of function was not permanent, the facility must submit the department-approved Functional Evidence form with supporting documentation to

the SET, and a RCA of the event is not required.

3.3.2.2 A facility is required to submit to the SET notification regarding a sentinel event involving a death or major permanent loss of function within 48 hours of treatment or procedure in an emergency department, ambulatory surgical facility, or end stage renal disease facility that is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in a healthcare facility.

3.3.2.3 A facility is required to submit notification regarding the suicide of a patient within 48 hours of discharge from a healthcare facility.

3.4 SET Case Review. Upon receipt of a notification or report of a sentinel event, the SET completes an initial review and may take other action that it determines to be appropriate pursuant to these rules. The facility must comply with the following requirements for the SET case review:

3.4.1 Provide a copy of the patient's medical record.

3.4.2 Provide a timeline of the event.

3.4.3 Present details of the event.

3.4.4 Schedule SET conference with the CEO or Administrator**.**

3.4.5 Schedule SET de-briefing regarding the findings with the facility.

~~3.1 Cooperation. A health care facility that has filed a notification or a report of the occurrence of a sentinel event, as required by these rules, must cooperate with the SET as necessary for the SET to fulfill its duties.~~

~~3.2 Initial review. Upon receipt of a notification or report of a sentinel event, the SET shall complete an initial review and may take other action that the SET determines is appropriate according to these rules.~~

~~3.3 On-site reviews. The SET may conduct on-site reviews of medical records and may retain the services of consultants when determined necessary by the SET.~~

~~3.4 Annual SET Report. On or before February first of each calendar year, the SET shall submit an annual sentinel events report to the Legislature,~~

~~healthcare facilities, and the public.The report must include summary data of the number and types of sentinel events for the prior calendar year, including~~

~~3.4.1.a compilation of data by type of healthcare facility;~~

~~3.4.2 a compilation of data by rates of change and other analyses; and~~

~~3.4.3 an outline of areas to be addressed during the next 12 months.~~

~~3.5 Civil Penalties. A healthcare facility that knowingly violates any provision of the sentinel events reporting law or rules is subject to a civil penalty payable to the State of not more than $5000 per unreported sentinel event to be recovered in a civil action. Funds collected pursuant to this rule must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.~~

Section 4. Root Cause Analysis (RCA).

4.1 **RCA Required**. The healthcare facility is required to submit to the SET a thorough and credible root cause analysis no later than 45 days after notification of the sentinel event. The RCA may exclude protected professional competence review information pursuant to the Maine Health Security Act, Title 24 M.R.S.A. Chapter 21.

4.2 **RCA Report**. The RCA must be submitted in an envelope labeled 'confidential' and the written report must contain at least the following:

4.2.1 Facility-specific unique identifier provided by the SET.

4.2.2 The root cause analysis.

4.2.3 Signature of the chief executive officer (CEO) of the facility.

4.2.4 Other information significant to the identification of systems improvements with the goal being prevention of the recurrence of a similar sentinel event, including but not limited to the following:

4.2.4.1 The final timeline of events.

4.2.4.2 Identification of the occurrence of a similar event or events.

4.2.4.3 Evidence of evaluation of the corrective actions implemented as a result of the similar event or events,

4.2.4.4 Evidence of communication with the receiving facility in the event of an inter-facility transfer.

4.2.4.5 An action plan that includes at least the following:

4.2.4.5.1 Where improvement actions are planned, identification of who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the action will be evaluated.

4.2.4.5.2 Identification of actions and rationale that clearly and specifically address each proximal cause and contributing factor of the sentinel event.

4.3 **Thorough and Credible RCA.** An acceptable RCA must comply with the following:

4.3.1 A *thorough* root cause analysis includes at least the following information:

4.3.1.1 A determination of the human and other factors most directly associated with the sentinel event and the processes and systems related to its occurrence;

4.3.1.2 An analysis of the underlying systems and processes to determine where redesign might reduce risk;

4.3.1.3 An inquiry into all areas appropriate to the specific type of event;

4.3.1.4 An identification of risk points and their potential contributions to the event;

4.3.1.5 A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such an event in the future or a determination, after analysis, that no such improvement opportunities exist;

4.3.1.6 An action plan that identifies changes that can be implemented to reduce risks or formulates a rationale for not undertaking such changes; and,

4.3.1.7 Where improvement actions are planned, an identification of who is responsible for implementation, when the action will be implemented and how the effectiveness of the action will be evaluated.

4.3.2 A *credible* root cause analysis meets the following criteria:

4.3.2.1 It includes participation by the leadership of the healthcare facility and by the individuals most closely involved in the processes and systems under review;

4.3.2.2 It is internally consistent (that is, not contradict itself or leave obvious questions unanswered);

4.3.2.3 It provides an explanation for all findings, including those identified as "not applicable" or "no problem," and

4.3.2.4 It includes the consideration of any relevant literature.

4.4 Additional Information. The SET may request additional information regarding the RCA and action plan, and the facility must comply as follows:

4.4.1 The facility must submit its written response to the SET written request for additional information within 14 days of receipt of the request, and the response must be signed by the Chief Executive Officer.

~~Section 4. Confidential and Privileged Information~~

~~4.1 Access. The SET has access to all licensed facility records necessary to carry out the provisions of these rules. The records obtained by the SET are not available to the public except as allowed by law.~~

~~4.2 Federal law. These rules do not affect the obligations of the department relating to Federal law.~~

~~4.3 Confidential and privileged information. Notifications and reports of sentinel events filed pursuant to these rules and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.~~

~~4.3.1 Not subject to public access, discovery, or admissible as evidence. Privileged and confidential information subject to these rules is not:~~

~~4.3.1.1 Subject to public access under 1 M.R.S.A. Chapter 13, except for data developed from the reports that do not identify or permit identification of the healthcare facility;~~

~~4.3.1.2 Subject to discovery, subpoena or other means of legal compulsion for release to any person or entity; or~~

~~4.3.1.3 Admissible as evidence in any civil, criminal, judicial or administrative proceeding.~~

~~4.3.2 Not a waiver of privilege. The transfer of any information subject to these rules by a healthcare facility to the SET or to a national organization that accredits healthcare facilities may not be treated as a waiver of any~~

~~privilege or protection established by these rules, the sentinel events reporting law, or other applicable Maine laws.~~

~~4.3.3 Other privileges. These rules may not be construed to limit other privileges that are available under federal and state laws that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided by the Sentinel Events Reporting statute.~~

~~4.3.4 Exclusions. For the purposes of these rules, "privileged and confidential information" does not include:~~

~~4.3.4.1 Any final administrative action;~~

~~4.3.4.2 Information independently received pursuant to a third party complaint investigation conducted pursuant to department rules; or~~

~~4.3.4.3 Information designated as confidential under rules and laws of this State.~~

~~4.3.5 Security of information. The SET shall take appropriate measures to protect the security of any information that is subject to these rules.~~

Section 5. Near Miss Events.

5.1 **Voluntary Self-Reporting.** A healthcare facility may notify the SET of the occurrence of a near miss event (Section 1.15). Reports shall be made on department-approved forms and include requested documentation. 22 M.R.S.A. Sec. 8753 (5).

5.2 **Annual Near Miss Focus Areas.** Each September, the SET shall announce the selected specific targeted near miss areas that shall be the focus of in-depth analysis for the next calendar year. Near miss data shall be collected from self-reporting healthcare facilities and SET activities, including record reviews. The goal of an annual targeted focus is to provide meaningful data and analysis of lessons learned from near miss events.

5.3 **Report.** The Sentinel Events Annual Report shall include near miss aggregate data analysis for near miss detection methodologies, causative factors and safety improvements.

Section 6. Consumer Complaints; SET Compliance Review.

6.1 **Complaints.** Any person with a licensing complaint may contact the division's Intake and Complaints Unit at 1-800-383-2441. If, upon review, the division determines that the reported event constitutes a sentinel event, it is referred to the SET.

6.2 **SET On-site review.** The SET may conduct an announced and unannounced visit to any facility to achieve the following:

6.2.1 Determine compliance with these rules.

6.2.2 Perform reviews based on complaints received by the division.

6.2.3 Perform reviews based on third-party case identification.

6.2.4 Review documents including but not limited to medical records, RCA reports, and committee meeting minutes. Professional competence review information protected pursuant to the Maine Health Security Act is excluded.

6.3 **Consultant.** The SET may retain the services of consultants when determined necessary.

Section 7. Confidential and Privileged Information.

7.1 **Immunity.** A person who in good faith reports a near miss event, a suspected sentinel event or a sentinel event or provides a RCA pursuant to these rules is immune from any civil or criminal liability for the act of reporting or participating in the review conducted by the SET.

7.1.1 "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. These rules may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

7.2 **Federal law.** These rules do not affect the obligations of the department relating to federal law.

7.3 **Immediate Jeopardy**. The division personnel responsible for sentinel event oversight shall report to the division's licensing section only incidences of immediate jeopardy and each condition of participation in the federal Medicare program related to the immediate jeopardy for which the provider is out of compliance.

7.4 **Confidential and privileged information.** Communication with the division is privileged and confidential.

7.4.1 The division shall take appropriate measures to protect the security of any information to which these rules apply.

7.4.2 Notifications and reports filed pursuant to these rules and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.

7.4.3 Pursuant to these rules, privileged and confidential information is not:

7.4.3.1 Subject to public access under Title 1 M.R.S.A. Chapter 13, except for data developed from the reports that do not identify or permit identification of the healthcare facility;

7.4.3.2 Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or

7.4.3.3 Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

7.4.4 Pursuant to these rules, the transfer of any information by a healthcare facility to the division or to a national organization that accredits healthcare facilities may not be treated as a waiver of any privilege or protection established by applicable Maine laws.

7.4.5 These rules may not be construed to limit other privileges that are available under federal or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided by these rules.

7.4.6 For the purposes of these rules, "privileged and confidential information" does not include:

7.4.6.1 Any final administrative action;

7.4.6.2 Information independently received pursuant to a third party complaint investigation conducted pursuant to department rules; or

7.4.6.3 Information designated as confidential under the rules and laws of this State.

Section 8. Enforcement.

8.1 **Oversight.** The division shall place primary emphasis on ensuring effective corrective action by the facility.

8.2 **Financial Penalty.** When the division determines that a healthcare facility failed to report a sentinel event as required by these rules, the healthcare facility is subject to a financial penalty, payable to the State of Maine, of not more than $10,000 per violation.

8.2.1 Each failure to report is a separate violation.

8.2.2 If a facility in good faith notified the division of a suspected sentinel event and the division later determines it is a sentinel event, the facility is not subject to a penalty for that event.

8.2.3 Funds collected pursuant to these rules must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

8.3 **Notice of Imposition of Penalty.** The SET shall send written notice to the healthcare facility stating the amount of the financial penalty imposed for failure to report a sentinel event. The notice shall include but is not limited to the date of the event and the deadline for filing an appeal of the penalty.

8.3.1 Payment of the penalty is due within 10 days of receipt of the written notice of imposition of a penalty or the date of final agency action, whichever is later.

8.4 **Administrative Hearing.** To contest the imposition of a penalty, a healthcare facility must submit to the division a written request for an administrative hearing within 10 days of receipt of the notice of imposition of a penalty.

8.5 **Judicial Review.** Judicial appeal must be in accordance with 5 M.R.S.A. chapter 375, subchapter 7.

8.6 **Injunction to require compliance.** Notwithstanding any other remedies provided by law, the Office of the Attorney General may seek an injunction to require compliance with the provisions of these rules.

8.7 **District Court Complaint for violations.** The Office of the Attorney General may file a complaint with the District Court seeking injunctive relief for violations of these rules.

1. SURGICAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**[i]
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient.[ii] Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ■ Surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), level (spine). ■ Wrong site surgery, even if corrected intraoperatively, as long as the surgery had begun, based on the definition below. This event is not intended to capture: ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins*, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit). Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at the time a surgical mark is made on the patient. Placing a mark on the wrong body part does not in itself constitute wrong site surgery. *(more)*

[i] Implementation guidance amplifies statements in the event and additional specifications based on the experience of those organizations/entities that have implemented the reporting of the events and the recommendations of NQF Members and the public. As such, the guidance does not purport to be—nor is it required to be— either comprehensive or uniform across the events.

[ii] Except in the case of an emergency, a physician must obtain a patient's agreement (informed consent) to any course of treatment. Physicians are required to tell the patient anything that would substantially affect his or her decision. Such information typically includes the nature and purpose of the treatment, including its risks and benefits, and alternative courses of treatment, including risks and benefits. The American Medical Association definition of informed consent is "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention" (see www.ama-assn.org/ama/pub/category/4608.html).

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.	This event is intended to capture: ▪ Surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient. *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins*, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed., regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
C. Wrong surgical procedure performed on a patient	Defined as any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ▪ Insertion of the wrong medical implant into the correct surgical site. This event is not intended to capture: ▪ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins*, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., surgical suite, endoscopy unit).

(more)

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
D. Unintended retention of a foreign object in a patient after surgery or other procedure	Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).	This event is intended to capture: ■ Occurrences of unintended retention of objects at any point after the surgery ends, regardless of setting or of whether the object is removed. *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins*, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

(more)

2. PRODUCT OR DEVICE EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.	The term *detectable* is intended to capture contaminations that can be seen with the naked eye or with the use of detection mechanisms that are in general use; these contaminations are to be reported when they become known to the provider or healthcare facility. Detection mechanisms may include cultures and tests that signal changes in pH or glucose levels.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.	This event is intended to capture occurrences whether or not the use is intended or described by the device manufacturers' literature. The Food and Drug Administration defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: ■ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, ■ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or ■ intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	High-risk procedures, other than neurosurgical procedures, that include a small but known risk of air embolism are reportable under this event, including, but not limited to, those involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.

(more)

3. PATIENT PROTECTION EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Infant discharged to the wrong person		Stedman's Online Medical Dictionary defines an infant as a child under the age of one year.
B. Patient death or serious disability associated with patient elopement (disappearance)	Excludes events involving competent adults.	This event is not intended to capture death or serious disability that occurs due to circumstances unrelated to the elopement (after the patient is located). The term *competent adult* should be interpreted in accordance with prevailing legal standards.
C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare facility" (defined in box B, previously).
4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment involving drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.	This event is intended to capture: ■ The most serious medication errors, including occurrences in which a patient known to have serious allergies to specific medications/agents receives those medications/agents, resulting in serious harm or death. These events may occur as a result of failure to collect allergy information; failure to review available allergy information; failure to assure the availability of allergy information and prominently display it; or through other system failures that are determined by investigation to be the cause of the adverse event. ■ Occurrences in which a patient dies or suffers serious disability as a result of failure to administer a prescribed medication. ■ Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique. This event is not intended to capture: ■ Patient death or serious disability associated with allergies that could not reasonably have been known or discerned in advance of the event. ■ *All* situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability—only those that result in death or serious disability.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products		This event is not intended to capture: ■ Patient death or disability associated with organ rejection, other than those attributable to a hyperacute hemolytic reaction. ■ Patient death or disability when the cause is not detectable by ABO/HLA matching.

(more)

4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.	This event is not intended to create a new obligation; the organization's obligation is to report the event when it is made aware of the maternal death or serious disability either by re-admittance or by the patient's family. A low-risk pregnancy is defined as a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.[iii]
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		Hypoglycemia is defined as blood glucose levels <60mgdL (ICD-9, 251.0).
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	*Hyperbilirubinemia* is defined as bilirubin levels >30 mg/dl. *Neonate* refers to the first 28 days of life.	The organization's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3, if Stage 2 was recognized upon admission.	
G. Patient death or serious disability due to spinal manipulative therapy		Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.[iv]
H. Artificial insemination with the wrong donor sperm or wrong egg		The organization's obligation is to report the event when it is made aware of the occurrence.

(more)

[iii] NQF, *Serious Reportable Events in Healthcare: A Consensus Report,* NQF: Washington, DC; 2002
[iv] NQF, *Serious Reportable Events in Healthcare: A Consensus Report,* NQF: Washington, DC; 2002

5. ENVIRONMENTAL EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock/elective cardioversion.	This event is intended to capture: ■ Patient death or disability associated with unintended electric shock during the course of care or treatment. This event is not intended to capture: ■ Patient death or disability associated with emergency defibrillation during ventricular fibrillation or electroconvulsive therapies.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances		
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility		
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		The event is intended to capture instances in which restraints are implicated in the death; for example, the use led to strangulation/entrapment. Death/disability resulting from falls caused by lack of restraints would be captured under falls. Restraint is currently defined by the Joint Commission, by the Centers for Medicare and Medicaid Services, and by some states. If none of those definitions apply to an institution, the following definition, which is intended to comprise definitions from the named organizations, is offered: Restraint is defined as any method of restricting a patient's freedom of movement that: is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; that is not indicated to treat the patient's medical condition or symptoms; or that does not promote the patient's independent functioning.[v] *(more)*

[v] Adapted from the Joint Commission, Comprehensive Accreditation Manual *Refreshed Core;* 2006.

6. CRIMINAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		
B. Abduction of a patient of any age		
C. Sexual assault on a patient within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that may use the terms *sexual assault* or *simple assault* or *criminal sexual conduct*); however, the principle and intent remain regardless of the language required based on jurisdiction.
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms *first degree assault* or *second degree assault* or *battery*).

Statutory Authority

22 M.R.S.A. Chapter 1684

22 M.R.S.A. §42
22-A M.R.S.A. §205

Regulatory History
Public Law 2001, chapter 678, established laws governing the reporting sentinel events and instructed the department to adopted rules to implement chapter 678.

ADOPTED

Deleted sentinel events reporting provisions in the following:

10-144 C.M.R. Ch. 112	Regulations for the Licensure of General and Specialty Hospitals in the State of Maine.
10-144 C.M.R. Ch. 118	Regulations Governing the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation.
10-144 C.M.R. Ch. 125	Regulations Governing the Licensing of Ambulatory Surgical Facilities.
10-144 C.M.R. Ch. 126	Regulations Governing the Licensing and Functioning of End Stage Renal Disease Units/Facilities.

ADOPTED

[New] 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, replaces the sentinel events reporting provisions in 10-144 C.M.R. Chapters 112, 118, 125, and 126.

EFFECTIVE DATE:
January 1, 2009 – filing 2009-579

AMENDED